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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,841	01/19/1999	RICHARD G. OLSEN	CIR20013	8242

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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/10/2001

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/125,841

Applicant(s)

Olsen et al.

Examiner

Ron Schwadron

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 7, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above, claim(s) 1-28 and 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

1. Applicant's election of the invention of Group V, claims 29-35 in Paper no. 17 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See MPEP section § 818.03(a)).
2. Claims 1-28,36-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made without traverse in Paper No. 17.
3. In view of the fact that the instant application was filed under 35 U.S.C. 371, the previous restriction requirement should have been made under 35 U.S.C. 371 practice. The instant application lacks unity of invention (e.g. a special technical feature) because the claimed inventions were obvious over the prior art for the reasons enunciated in the 409 report included in the instant application and for the reasons enunciated in the prior art rejections in this Office Action. Therefore, the restriction requirement is maintained and applicants election is maintained.
4. Claims 29-35 are under consideration.
5. The instant application currently claims priority only to PCT 97/02309. Applicant could claim priority under 35 U.S.C. 120 to potential parent applications 08/604728 and 08/943993. If applicant decides to claim priority to said applications, applicant should:
  - a) amend the specification, page 1, line to claim priority to said applications,
  - b) submit a new declaration claiming priority to said applications,
  - c) submit a new sequence listing in paper and CRF forms listing the parent applications in section <150>.
6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
7. Claims 29-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention.

Claims 29-35 are indefinite in that they depend on nonelected claims 22-28. Claims 29-35 are indefinite in the recitation of "helper cells" because it is unclear what this means or encompasses. The term "helper cell" in itself has no art recognized meaning and is not defined in the specification. Therefore it is unclear what types of cells are encompassed by said term. A preferred substitution is "T helper cells".

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Babbitt et al. (US Patent 5,766,920).

Babbitt et al. teach expanded T helper cells from a patient which are expanded by treating mononuclear cells with antiCD3 antibody and IL-2 containing conditioned media (see column 2 and column 3, second paragraph). There is no evidence of record that the particular culture conditions recited in the claims would have any particular effect on the treated cells. Furthermore, the cells are produced by a method "comprising" and would therefore encompass the addition of other manipulations which would lead to the production of cells as per taught by the method of Babbitt et al. Babbitt et al. teach that this method can be used to produce cells from HIV patients (see column 7, third complete paragraph). While Babbitt et al. do not specifically teach that the cells used are obtained from lymph nodes of HIV patients, Babbitt et al. teach that lymph nodes are a known source of mononuclear cells (see column 2, third complete paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Babbitt et al. teach the claimed invention except for use of lymph node cells and Babbitt et al. teach that lymph nodes are a known source of mononuclear cells.

One of ordinary skill in the art would have been motivated to create the claimed invention because Babbitt et al. teach expanded T helper cells from a patient (including HIV infected) which are expanded by treating mononuclear cells with antiCD3 antibody and IL-2 containing conditioned media and that lymph nodes are a known source of mononuclear cells.

10. Claims 29-35 are rejected under 35 U.S.C. § 103 as being unpatentable over Ochoa et al. (US Patent 5,443,983) in view of prior art disclosed in the specification (page 4, lines 19-22).

Ochoa et al. teach that T cells from HIV patients can be cultured with antiCD3 antibody and IL-2 (see Abstract) resulting in the generation of T cells. While Ochoa et al. teaches that these cells are LAK cells, because the cells are from the same source and treated in the same manner as the cells of the claimed invention they would be expected to contain enriched T helper cells. Ochoa et al. teaches that the lymphocytes are preferably obtained from the individual (eg. HIV positive AIDS patient) to be treated. While Ochoa et al. do not specifically teach the use of lymph node cells, Ochoa et al. does teach that the cells used as a starting product can be derived from any tissue which is a source of lymphocytes (eg. lymph nodes). Furthermore, the specification discloses that art recognized that lymph node derived cells would have a superior locomotor ability and ability to traffic to lymph nodes in comparison to PBL (page 4, lines 19-22). Ochoa et al. teach that any art known media (eg. serum-free macrophage media) can be used to grow T cells as long as said media supports T cell growth (column 3, third paragraph). A routineer would have derived the particular dosage of IL-2 and antiCD3 antibody used in the instant invention by routine experimentation. Ochoa et al. teaches that said cells can be cultured with antiCD3 antibody and IL-2 for any desired period of time (see column 3, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Ochoa et al. teach that T cells from HIV patients can be cultured with antiCD3 antibody and IL-2 (see Abstract) and that the cells used as a starting product can be derived from any tissue which is a source of lymphocytes (eg. lymph nodes) while the prior art recognized that lymph node derived cells would have a superior locomotor ability and ability to traffic to lymph nodes in comparison to PBL.

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON  
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Art Unit 1644  
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